K010245

1 of 2

APR 2 5 2001

Attachment 3

Summary of Safety and Efficacy Summary of Advanced Medical Solutions Flexipore Scar Management Dressing

Manufacturer:	Advanced Medical Solutions, Group plc Road Three, Winsford Industrial Estate Cheshire CW7 3PD, United Kingdom
Regulatory Affairs Contact:	Christopher Oakes, Manager
Telephone:	44 1606 54 5611
Date Summary Prepared:	January 22, 2001
Device Trade Name:	Flexipore Scar Management Dressing
Common or Usual Name:	Dressing Wound Occlusive
Classification:	Class 1
Description:	Advanced Medical Solutions Flexipore Scar Management dressing can be supplied as either a bi-laminate or tri-laminate polyurethane dressing. The dressing consists of either two layers, the outer surface consists of a polyurethane microporous membrane, the inner surface is an acrylic pressure sensitive adhesive, or three layers with the outer surface consisting of a polyurethane film, the middle layer of a polyurethane microporous membrane, the inner surface is an acrylic pressure sensitive adhesive The dressing is to aid in the management of both existing and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds. The Advanced Medical Solutions Flexipore Scar Management dressing comes in various pack sizes. The Advanced Medical Flexipore Scar Management dressing is self-adhesive and the adhesion in itself gives the compression characteristics required. The dressing is supplied for use in the non-sterile format.
Intended Use:	The Advanced Medical Solutions Flexipore Scar Management dressing is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds. If redness, pain, and/or irritation occur, discontinue use and consult a healthcare professional

K010245
2 of 2

Not for use on third degree burns.

Not to be used on open wounds.

Not for patients with dermatological conditions which disrupt the integrity of the skin in areas of coverage.

Substantial Equivalence:

Substantial equivalence was provided in 510(k)'s Flexipore Skin Protector K953885 and Advanced Medical Solutions Silicone Scar Management Sheet K991630.

Testing Summary:

Biocompatabilty summary is presented in Attachment 4 of this submission.All tests performed in accordance with ISO10993-1 show the product to be non toxic and harmless for its intended application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2001

Mr. Christopher Oakes
Regulatory Affairs Manager
Advanced Medical Solutions Group Limited
Road Three
Winsford Industrial Estate
Cheshire CW7 3PD
United Kingdom

Re: K010245
Trade/Device Name: Advanced Medical Solutions Flexipore
Scar Management Dressings
Regulatory Class: Unclassified
Product Code: MDA
Dated: January 22, 2001
Received: January 25, 2001

Dear Mr. Oakes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010245

510(k) Number (if known): K010245

Device name: Advanced Medical Solutions Flexipore Scar Management Dressings

Indications For Use:

Advanced Medical Solutions Flexipore Scar Management Dressings are intended for OTC use for the management of:

Old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR Over The Counter Use X

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010245